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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,897	12/16/2005	Masayuki Yabuki	269077US0PCT	2267
22850	7590	04/06/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER MA, JAMESON Q	
			ART UNIT	PAPER NUMBER
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			04/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/529,897	Applicant(s) YABUKI ET AL.	
	Examiner JAMESON Q. MA	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 11-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20050422, 20050816</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group II and species A in the reply filed on 1/12/2009 is acknowledged. The traversal is on the ground(s) that no adequate reasons have been provided to support a conclusion of patentable distinctness between identified groups. This is not found persuasive because it has been shown that the special technical feature has not been found to be a contribution over the prior art. It is also noted that in a lack of unity requirement *a posteriori*, that there is no burden on the examiner to explain why each group lacks unity with each other group. Further, it is the position of the examiner that the claims have been interpreted in light of the description and that the burden necessary to support the assertion of a lack of unity has been met. Regarding applicants citation of 37 C.F.R. § 1.475(b), the examiner draws attention to 37 C.F.R. § 1.475(c), which states:

“If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 and 12-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and species, there being no allowable generic or linking claim. It is further noted that the examiner has withdrawn

Art Unit: 1797

claim 25, because it does not appear to read on the elected species as asserted by applicant. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/12/2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 31-33 recites the limitation "the reagent". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Yabuki et al. (The study of human odor. A new odorant in axillae).

Regarding claims 8-10, Yabuki discloses that axillary sweat was extracted from subjects with a strong apocrine odor and were analyzed using a GC-MS (viewed as a method of assessing body odor). Yabuki discloses that the important components that produce the typical odor of axillary sweat were determined by a sniffing GC, see P125:

Art Unit: 1797

Experimental. Yabuki discloses that in an investigation of axillary odorants, the compound 3-hydroxy-3-methylhexanoic acid was identified (see 'Results and Discussion' and Fig. 4). Therefore it is interpreted by the examiner that 3-hydroxy-3-methylhexanoic acid is used as an index and as an indicator material in the assessment of odor by GC/MS.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1797

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 8-10 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US 2003/0100842) in view of Labows et al. (Axillary Odor: determination, formation and control) and Yabuki et al. (The study of human odor. A new odorant in axillae).

Regarding claims 8-10 and 31, Rosenberg discloses a method for indicating a level of bad breath (oral malodor), see [0005]. Rosenberg discloses that a practical problem is that oral malodor measurements are not reliable. Rosenberg further discloses that bad breath is measured by the level of halitosis (bad breath) was measured by taking a sample of saliva and subjecting the saliva to a colorimetric test for a compound correlated to bad breath. This colorimetric test is then compared to a standard color scale to determine the level of bad breath, see [0013-0018] and [0031-0032].

Rosenberg fails to disclose the use of a beta hydroxycarboxylic acid in the method.

Labows teaches that in body odor perception, the absolute threshold (the lowest concentration perceived) can be used to determine the relative sensitivity of individuals to odorants. Labows further teaches that in many situations, individuals do not perceive, and thus may not be able to interpret human odors in the same manner, see P10/Paragraph A. Labows further discloses that humans have anosmias (lack of

Art Unit: 1797

olfaction) to many types of odors including axillary, foot, breath, and semen (see Table 2).

Yabuki discloses that in an investigation of axillary odorants, the compound 3-hydroxy-3-methylhexanoic acid was identified as an axillary odorant (see 'Results and Discussion' and Fig. 4).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the method taught by Rosenberg to indicate a level of axillary odor in a colorimetric method because as taught by Labows, the relative characterization of axillary odor by individuals suffers from a similar lack of reliability due to individual variances and anosmias as the oral malodors taught by Rosenberg. It further would have been obvious to one of ordinary skill in the art to select 3-hydroxy-3-methylhexanoic acid as the representative axillary odorant, because doing so would have resulted in nothing more than the selection of a finite number of identified and predictable axillary odorants as set forth by both Labows and Yabuki.

For claims 32 and 33, modified Rosenberg does not disclose that the beta hydroxycarboxylic acid is separated from a fatty acid having 12 or less carbons, and that the separated mixtures are separately subjected to a coloring reagent and that the assessment of the kind of body odor is exhibited from both reactions. However, Labows teaches that different axillary odorants have different primary odors such as urinous, musky, sweaty, or hircine (see Table 2). Yabuki teaches that 3-hydroxy-3-methylhexanoic acid and fatty acids having less than 12 carbons can be present in the same sample of axillary sweat (see figure 4). It would have been obvious to one of

Art Unit: 1797

ordinary skill in the art at the time of invention to isolate the different axillary odorants taught by both Labows and Yabuki, and subject each isolate to a colorimetric test in order to further determine the specific levels of ruinous, musky, sweaty and hircine odorants as taught by Labows.

12. Claims 8-10 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US 2003/0100842) in view of Labows et al. (Axillary Odor: determination, formation and control) and Natsch et al. (US 7,264,956).

Regarding claims 8-10 and 31, Rosenberg discloses a method for indicating a level of bad breath (oral malodor), see [0005]. Rosenberg discloses that a practical problem is that oral malodor measurements are not reliable. Rosenberg further discloses that bad breath is measured by the level of halitosis (bad breath) was measured by taking a sample of saliva and subjecting the saliva to a colorimetric test for a compound correlated to bad breath. This colorimetric test is then compared to a standard color scale to determine the level of bad breath, see [0013-0018] and [0031-0032].

Rosenberg fails to disclose the use of a beta hydroxycarboxylic acid in the method.

Labows teaches that in body odor perception, the absolute threshold (the lowest concentration perceived) can be used to determine the relative sensitivity of individuals to odorants. Labows further teaches that in many situations, individuals do not perceive, and thus may not be able to interpret human odors in the same manner, see P10/Paragraph A. Labows further discloses that humans have anosmias (lack of

Art Unit: 1797

olfaction) to many types of odors including axillary, foot, breath, and semen (see Table 2).

Natsch discloses that 3-hydroxy-3-methylhexanoic acid has a pungent odor, and is a key malodour volatile in human sweat (see C3/L18-25).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the method taught by Rosenberg to indicate a level of axillary odor in a colorimetric method because as taught by Labows, the relative characterization of axillary odor by individuals suffers from a similar lack of reliability due to individual variances and anosmias as the oral malodors taught by Rosenberg. It further would have been obvious to one of ordinary skill in the art to select 3-hydroxy-3-methylhexanoic acid as the representative axillary odorant, because doing so would have resulted in nothing more than the selection of a finite number of identified and predictable axillary odorants as set forth by both Labows and Natsch

For claims 32 and 33, modified Rosenberg does not disclose that the beta hydroxycarboxylic acid is separated from a fatty acid having 12 or less carbons, and that the separated mixtures are separately subjected to a coloring reagent and that the assessment of the kind of body odor is exhibited from both reactions. However, Labows teaches that different axillary odorants have different primary odors such as urinous, musky, sweaty, or hircine (see Table 2). Yabuki teaches that 3-hydroxy-3-methylhexanoic acid and fatty acids having less than 12 carbons can be present in the same sample of axillary sweat (see figure 4). It would have been obvious to one of ordinary skill in the art at the time of invention to isolate the different axillary odorants

Art Unit: 1797

taught by both Labows and Yabuki, and subject each isolate to a colorimetric test in order to further determine the specific levels of ruinous, musky, sweaty and hircine odorants as taught by Labows.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-R 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

March 23, 2009